REMARKS

Initially, Applicant would like to thank the Examiner for granting a telephone interview on May 21, 2004. A letter outlining issues to be discussed in the interview was sent to the Examiner on May 20, 2004 (copy attached hereto as "Exhibit A"). This letter and the remarks below serve as a summary of the interview.

In the Final Office Action dated December 23, 2003, the Examiner rejected all pending claims as being obvious. Among the rejected claims, claims 33 and 51 are independent claim. Claim 33 covers a viral expression vector that contains, among others, an enhancer having SEQ ID NO:1 or its complement. The other independent claim, claim 51, covers an expressing method that requires using the vector of claim 33. It is the Examiner's position that the claims are obvious over Zhang (which teaches a non-viral expression vector that has a SEQ ID NO:1-containing HS40 enhancer) in view of Miller (which teaches retroviral vectors containing promoters). According to the Examiner, it would have been obvious to one skilled in the art to include in the Miller vectors the HS40 enhancer taught in Zhang. In the response dated March 22, 2004, Applicant pointed out that it is well known in the art that an enhancer that functions in a non-viral vector, such as the Zhang vector, may not function in a viral vector. As a result, one skilled in the art would not have been motivated to make a viral vector containing an enhancer in the way the Examiner suggested. To support this point, Applicant submitted a copy of McCune, which teaches that (1) an enhancer functions well in a non-viral vector, but fails in a viral vector and (2) viral vector sequences are responsible for the failure. In the Advisory Action, the Examiner countered that the "element as taught by McCune is not limited to the responsible element as claimed[,] i.e., SEQ ID NO:1, therefore ... any response element other than as taught by McCune would be able [to] function in any viral ... vector."

During the telephone interview, Applicant pointed out that McCune provides a general teaching about inhibiting effects of viral vector sequences on enhancers. See the title of McCune. Indeed, McCune specifically teaches that "[its] finding may be applicable to the more general problem of sustaining expression of retrovirus-transduced genes... (see page 4477, column 2, lines 12-13)." Given this general teaching, one skilled in the art would not expect that

an enhancer, including one containing SEQ ID NO:1, may function in a viral vector, even though it may function well in a non-viral vector. Due to lack of a reasonable expectation of success, one skilled in the art would have not been motivated to include in the Miller vectors the HS40 enhancer taught in Zhang. Thus, Zhang and Miller do not render claim 33 or 51 obvious. In view of Applicant's remarks, the Examiner contended that contradictory conclusions could be drawn based on Zhang and Miller, or based on McCune, Zhang and Miller, and suggested that independent claims 33 and 51 be amended to recite "ζ-globin."

For the sole purpose of moving this case toward allowance, Applicant has amended independent claims 33 and 51 and filed herewith a Request for Continued Examination, as suggested by the Examiner. Support for "ζ-globin" can be found at e.g., page 1, lines 1-2, and lines 30-31. No new matter is introduced. It is submitted that claims 33 and 51 are in condition of allowance.

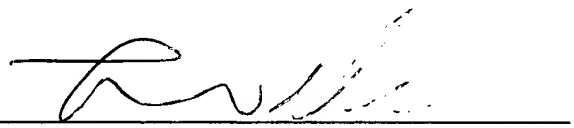
Of note, in the Final Office Action and Advisory Action, the Examiner also rejected certain claims, which depend from claim 33 or 51, over Zhang in view of Miller and Jarman. As pointed out in the response filed March 22, 2004, Jarman does not rectify the deficiencies of Zhang and Miller. Thus, these three references do not render claim 33 or 51 obvious. Neither do they render obvious claims dependent from claim 33 or 51. As claims 33 and 51, as amended, are allowable, so are these claims.

In view of the above amendments and remarks, as well as the remarks provided in the last response, Applicant submits that the grounds for the rejections asserted by the Examiner have been overcome, and that claims, as pending, define subject matter that is non-obvious. On this basis, it is submitted that allowance of this application is proper, and early favorable action is solicited.

This response is being filed concurrently with a Request for Continued Examination and the required $385.00 fee. Also enclosed is a $210 check for the Petition for Extension of Time fee. Please apply any other charges to Deposit Account No. 06-1050, referencing Attorney Docket No. 08919-016003.

Respectfully submitted,

Date: 5-24-2004



Jianming Hao
Reg. No. 54,694

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

2511cf58.doc

FISH & RICHARDSON P.C.

225 Franklin Street
Boston, Massachusetts
02110-2804

Telephone
617 542-5070

Facsimile
617 542-8906

Web Site
www.fr.com

Frederick P. Fish
1855-1930

W.K. Richardson
1859-1951

VIA FACSIMILE

May 20, 2004

Examiner Kaushal Sumesh
U.S. Patent & Trademark Office
Commissioner for Patents
Washington, D.C. 20231

Re: HS-40 ENHANCER-CONTAINING VECTOR
Applicant: Chen-Kun James Shen
Application No.: 09/977,432
Our Ref.: 08919-016003

BOSTON
DALLAS
DELAWARE
NEW YORK
SAN DIEGO
SILICON VALLEY
TWIN CITIES
WASHINGTON, DC

Dear Examiner Sumesh:

Thank you for granting a telephone interview, scheduled for 2:00 pm, May 21, 2004 to resolve issues raised in the Final Office Action and the Advisory Action. This letter is limited to claim 33 to facilitate discussion.

Claim 33 covers a viral expression vector that contains, among others, an enhancer having SEQ ID NO:1 or its complement. You rejected this claim as being obvious over Zhang (which teaches a non-viral expression vector that has a SEQ ID NO:1-containing HS40 enhancer) in view of Miller (which teaches retroviral vectors containing promoters). It is your position that it would have been obvious to one skilled in the art to include in the Miller vectors the HS40 enhancer taught in Zhang.

In the response dated March 22, 2004, we pointed out that it is well known in the art that an enhancer that functions in a non-viral vector, such as the Zhang vector, may not function in a viral vector. As a result, one skilled in the art would not have been motivated to make a viral vector containing an enhancer in the way you suggested. To support this point, we submitted a copy of McCune, which teaches that (1) an enhancer functions well in a non-viral vector, but fails in a viral vector and (2) viral vector sequences are responsible for the failure.

In the Advisory Action, you countered that the "element as taught by McCune is not limited to the responsible element as claimed[,] i.e., SEQ ID NO:1, therefore ... any response other than as taught by McCune would be able [to] function in any viral ... vector." As you correctly pointed out, McCune is not limited to SEQ ID NO:1. Nonetheless, we note that McCune provides a general teaching about inhibiting effects of viral vector sequences on enhancers. See the title. Indeed, McCune specifically teaches that "[its] finding may be applicable to the more general problem of sustaining expression of retrovirus-transduced genes... (see page 4477, column 2, lines 12-13)." Given this general teaching, one skilled in the art would not expect

that an enhancer, including one containing SEQ ID NO:1, may function in a viral vector, even though it may function well in a non-viral vector. Due to lack of a reasonable expectation of success, one skilled in the art would have not been motivated to include in the Miller vectors the HS40 enhancer taught in Zhang. Thus, Zhang and Miller do not render claim 33 obvious.

As the next deadline falls on May 24, 2004, we would like to expedite the prosecution by inviting your primary Examiner Mr. Jeffrey Fredman to the interview. If you agree, please provide a copy of this letter to him before the interview.

We look forward to speaking to you.

Very truly yours,

Y. Rocky Tsao

Y. Rocky Tsao, Ph..D., J.D.
Reg. No. 34,053

20866000.doc